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5600 FISHERS LANE  
ROCKVILLE, MARYLAND 20852

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

[21 CFR PART 500]

[DOCKET NO. 75P-0132]

TRICHLOROETHYLENE

PROHIBITION IN ANIMAL AND PET FOOD

42 FR 49468  
9-27-77

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: This proposal would prohibit use of trichloroethylene in animal feed or pet food, because it may pose a risk of cancer in man and animals. This action ensues from a National Cancer Institute report and a petition of the Health Research Group concerning trichloroethylene.

DATES: Comments by (insert date 60 days after date of publication in the FEDERAL REGISTER). The Commissioner of Food and Drugs expects to issue final regulations based on this proposal no later than (insert date 120 days after date of publication in the FEDERAL REGISTER), which shall be effective upon the date of their publication in the FEDERAL REGISTER.

ADDRESSES: Written comments to the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

76-809

NPR 1

FOR FURTHER INFORMATION CONTACT:

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Food and Drug Administration,  
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(301-443-3183).

SUPPLEMENTARY INFORMATION: The Commissioner is proposing to add new § 500.48 (21 CFR 500.48) to list trichloroethylene among substances prohibited from use in animal feed or pet food.

Elsewhere in this issue of the FEDERAL REGISTER, FDA is proposing: (1) to amend the food additive regulations to delete provisions for use of trichloroethylene in the manufacture of foods and food contact surfaces; (2) to amend the color additive regulations to delete provisions for use of trichloroethylene in the manufacture of color additives; (3) to declare that any human or animal drug product containing trichloroethylene is a new drug or new animal drug and deemed to be misbranded; (4) to declare that any cosmetic product containing trichloroethylene is deemed to be adulterated; and (5) to declare that food containing trichloroethylene is deemed to be adulterated. Those actions and this proposal are based on the National Cancer Institute (NCI) report entitled "Carcinogenesis Bioassay of Trichloroethylene." The report presents a synopsis of the results of a carcinogenesis bioassay of trichloroethylene using mice and rats and concludes that trichloroethylene induces liver cancer in mice. The report is summarized in the proposal to repeal the food additive uses of trichloroethylene.

In a petition dated June 24, 1975, the Health Research Group (HRG), 2000 P St. NW., Washington, DC 20036, requested that the Commissioner revoke the food additive tolerance established for trichloroethylene. In support of this request, HRG cited the "memorandum of alert" issued by NCI on March 21, 1975, on the possible carcinogenicity of trichloroethylene. The Health Research Group also referred to a March 20, 1975 interagency memorandum to the Associate Director for Carcinogenesis, NCI, which stated that "Preliminary evaluation of results of the carcinogenesis testing of trichloroethylene indicates that the compound is carcinogenic in mice." The petition by HRG stated that "the preliminary evaluation of results has now been confirmed." After receiving the HRG petition, NCI reemphasized that its memorandum of alert referred only to preliminary data, which had yet to be confirmed by further analysis of current studies.

If the proposal set forth below and the related proposals published in this issue of the FEDERAL REGISTER are adopted, the action sought by HRG will be effected, and further action regarding the petition will be unnecessary.

Copies of the NCI report and the HRG petition have been placed on public display at the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Having evaluated the available data, the Commissioner concludes that the NCI report demonstrates that trichloroethylene is a carcinogen in test animals. Accordingly, under section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A)), which is known as the Delaney clause, the use of trichloroethylene as a food additive may no longer be approved. The Commissioner therefore proposes to amend the animal feed regulations to prohibit use of trichloroethylene as a component of animal feed or pet food. The Commissioner expects to issue the final regulation prohibiting the use of trichloroethylene as an animal food additive (directly or indirectly) no later than (insert date 120 days after date of publication in the FEDERAL REGISTER); it shall be effective upon publication, under section 409(e) of the act (21 U.S.C. 348(e)).

The Commissioner has been advised that trichloroethylene-extracted oil-seed products have been found to contain an unidentified substance that is toxic to farm animals. Trichloroethylene-extracted soybean meal has been reported as causing heavy losses in cattle and sheep due to aplastic anemia and internal hemorrhages. Based on this information, trichloroethylene-extracted oil-seed products are considered toxic to animals.

The Commissioner advises that he is not aware of any data to show that trichloroethylene is a human or animal (other than laboratory animal) carcinogen. Additionally, he advises that the food products in which the trichloroethylene residue tolerances have been established are greatly diluted in the finished foods. He also advises that only small amounts of trichloroethylene remain in food-packaging adhesives or vinyl chloride-hexene-1 copolymers from its permitted uses, and only a very small amount of trichloroethylene could migrate into food from these food-contact articles. Therefore, the Commissioner concludes that the potential risk to the public health is not sufficient to require removal from the market of foods or food-contact articles containing trichloroethylene or the issuance of a public warning against the use of these products. Consequently, the Commissioner is of the opinion that the public health would be adequately served by permitting the use of existing stocks of products containing trichloroethylene that were manufactured before the effective date of the final regulation, but prohibiting any future use of trichloroethylene as a food additive or an additive in animal feed.

The Commissioner has carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 402, 403, 409, 701, 52 Stat. 1046-1048 as amended, 1055-1056 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 342, 343, 348, 371)) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 500 be amended by adding new § 500.48 to Subpart B to read as follows:

§ 500.48 Substances prohibited from use in animal feed or pet food.

(a) The food ingredients listed in this section have been prohibited from use in animal food by the Food and Drug Administration because of a determination that they present a potential risk to the public health or have not been shown by adequate scientific data to be safe for use in animal food. Use of any of these substances

in violation of this section causes the food involved to be adulterated in violation of the act.

(b) This section includes, for easy reference, only a partial list of substances prohibited from use in animal food; it is not a complete list of substances that may not lawfully be used in animal food. No substance may be used in animal food unless it meets all applicable requirements of the act.

(c) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish, amend, or repeal a regulation under this section on the basis of new scientific evaluation or information. Any such petition shall include an adequate scientific basis to support the petition, shall be in the form set forth in § 10.30 of this chapter, and will be published in the FEDERAL REGISTER for comment if it contains reasonable grounds.

(d) Substances prohibited from direct or indirect addition, or use in animal food are the following:

(1) Trichloroethylene. (i) Trichloroethylene is the chemical 1,1,2-trichloroethene,  $C_2HCl_3$  [Chemical Abstracts Service Registry No. 79-01-6]. It is a synthetic chemical having the characteristics of a volatile, nonflammable solvent, not found in natural products at levels detectable by the official methodology and has been used as a solvent in the extraction of certain oil-seed products. These products have been found to contain an unidentified substance that is toxic to farm animals.

(ii) Animal food containing any added or detectable level of trichloroethylene is deemed to be adulterated in violation of the act upon an order published in the FEDERAL REGISTER of (insert date of publication of final regulation in the FEDERAL REGISTER).

(2) [Reserved]

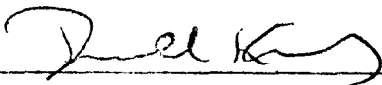
Interested persons may, on or before (insert date 60 days after date of publication in the FEDERAL REGISTER) submit to the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

The Food and Drug Administration has determined that this document does not contain a major proposal requiring preparation of an economic impact statement under Executive Order 11821 and OMB Circular A-107.

Dated: \_\_\_\_\_

9/19/77

SEP 19 1977



Donald Kennedy  
Commissioner of Food and Drugs

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Deborah A. Cera